

REMARKS

Claims 1 and 3-18 are pending. Claim 1 has been amended by replacing the limitation "alkyl celluloses" with "methylcellulose, hydroxyalkylcelluloses." Support for this amendment is found, for example, on page 4, 9th to 11th lines. Claim 3 has been amended in its dependency, to depend from claim 1, mooted the objection to this claim from the last office action. No new matter is introduced hereby.

Objection to Claim

The Examiner has objected to claim 2 as dependent from a cancelled claim, whereas Applicants believe that the Examiner meant to object to claim 3, which should be amended to depend from claim 1. This amendment has been carried out, and the objection is believed to be mooted thereby.

Rejection Under 35 U.S.C. §102 (b) Over Bai (United States Patent No. 5,840,329)

Claims 1, 3-15, 17 and 18 have been rejected as anticipated by Bai. Applicants respectfully traverse the rejection for the following reasons.

Bai discloses pre-programmed drug delivery systems including a plurality of particles, "divided into several delivery units, with each group having its own unique inner structured active core and specific external coating." (col. 3, lines 49-51). The particles "contain an **outer coating** of a major portion of water-insoluble, water-permeable polymer, and a minor portion of water-insoluble, water-swellaable polymer, and water permeation adjusting agents..." (col. 3, lines 56-59; emphasis added). As Bai explains, in the preferred embodiment "major portion of water-insoluble, water-permeable polymer" means "from 80% to 99.9%" and "minor portion of water-insoluble, water-swellaable polymer" means "from 0.1% to 20%" (col. 8, lines 57-61).

Applicants have claimed a composition comprising "a film-forming material comprising methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers, methyl cellulose, hydroxyalkylcelluloses or mixtures thereof, in combination with a high-viscosity swellaable polymer." Each of the claimed types of film-forming materials will now be compared with the disclosure of the cited reference.

Firstly, the Examiner points out that Bai discloses "Carbopol" at col. 9, line 27. Carbopol is an acrylic acid polymer.

Applicants on the other hand, have claimed a composition comprising "film-forming material comprising ...methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers..." Bai does not disclose any methacrylic acid copolymers, nor any polymethacrylate-methylmethacrylate copolymers.

Secondly, the Examiner points out that Bai discloses "cellulose (mono-, di-, or tri-) alkanylate" at col. 9, line 27. This terminology is not believed to be common usage,¹ but the form of the nomenclature indicates an ester, where the cellulose provides the alcoholic portion, and the alkanylate provides the acidic portion.

Applicants on the other hand, have claimed a composition comprising "film-forming material comprising ... methyl cellulose, hydroxyalkylcelluloses..." Such materials are cellulose ethers, and are distinct from "cellulose (mono-, di-, or tri-) alkanylate" materials disclosed in Bai.

In summary, the water-insoluble, water-permeable polymers of Bai's external coating layer (again, required to be present in a major portion by Bai) which are considered suitable by Bai are listed in col. 9, lines 23-46. There is no disclosure of any of "methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers, methyl cellulose, hydroxyalkylcelluloses or mixtures thereof," as required by the pending claims.

Because there is no disclosure in Bai of required components of Applicants' coating composition of pending claim 1, and because all other pending claims depend from claim 1, there is no anticipation of Applicants' claims by Bai. The Examiner is respectfully requested to reconsider and withdraw the rejection.

¹ A search of the USPTO patent database shows that only two issued U.S. Patents (US 6,510,561 and the cited patent to Bai) contain both terms "cellulose" and "alkanylate" in their specifications.

Rejection Under 35 U.S.C. §103 (a) Over Bai (United States Patent No. 5,840,329) and Jain et al. (United States Patent No. 4,610,870)

Claims 15 and 16 have been rejected as obvious over the combined disclosures of Bai and Jain et al. Applicants respectfully traverse the rejection for the following reasons.

The Examiner points out that Jain et al. discloses polyethylene glycol as a plasticizer (col. 7, lines 20-24), and asserts that a *prima facie* case of obviousness is made out by this combination. However, it is well recognized that a *prima facie* case of obviousness cannot be made out when the combination of references does not contain each limitation of the claim alleged to be unpatentable. In re Royka, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974). As the rejected claims depend from claim 1, they each contain all the limitations of claim 1.

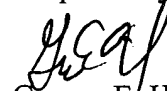
As pointed out above, the disclosure of Bai does not provide “a film-forming material comprising methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers, methyl cellulose, hydroxyalkylcelluloses or mixtures thereof.” The same is true of Jain et al. Jain et al. does not disclose or otherwise suggest the use of such film forming materials. Thus, a *prima facie* case of obviousness is not made out in this case.

Applicants thus respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

The claims are believed to be patentably distinct from the cited references, and with this in mind, Applicants respectfully request a Notice of Allowance at the earliest opportunity.

Respectfully submitted,



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